Application Ctrl Number - 10/801,520

MAZZIO AND SOLIMAN - 1st Amendment

----FIRST AMMENDMENT---



SECTION 1: INTRODUCTORY COMMENTS.

The following is a summary of actions, and claim amendments.

- 1. 35 USC 112 2ND P- <u>CLAIMS 2-13 ARE INDEFINITE</u>: The structure of these claims regarding % weight was indefinite. The original submission had a broad range and then a specified concentration "about x%" in the same claim. Secondly, the % weight did not specify as to the weight of active ingredients or weight of total composition. <u>An amendment</u> is being filed where further dependent claims are added (new claims 22-32) to separate the broad range from a more specific concentration. And, the % as weight is further defined in all applicable claims as a percentage of total composition (claims 2-9,12-13,22-32).
- 2. 35 USC 112 2ND P-CLAIM 10 IS INDEFINITE by the phrase "wherein said propolis can be substituted for garlic". If we can not ameliorate this issue, we would like to cancel this claim in its entirety. Claim 1 has been ammended to reflect propolis as an alternative for garlic. In the specification ie . Paragraph [00019], we briefly discuss potential adverse effects of garlic in some individuals, and therefore included propolis as an optional replacement for garlic due to analogous function, serving as a less allergenic component. However, we also disclose that propolis was not tested in the original formulation.
- 3. 35 USC 112 2ND P -CLAIM 12 IS UNCLEAR as to what are niacin derivatives. This claim is being amended to define niacin derivatives as specific forms of the compound.

4. 35 USC 102 (B) <u>CLAIMS 1-16: – RELEVANT PRIOR ART</u>

The prior art of Burachevskii, Kimura, Terry, Dr Clark, Matsui, Minetti, Kidena, Hamada, Buyn/Mabberly, Scivoletto, Tereshinko and Detsina were reviewed and deemed appropriate. An amendment is being filed to claim 1, which is the broadest independent claim. In the application as filed, the original language structure of claim 1 was limiting due to the large number of formulations that exist and contain a compound selected from claim 1a [wormwood, blackwalnut or niacin], combined with one selected from claim 1c [tumeric, garlic, st Johns wort, licorice, chamomile and herbal anti-bacterial agents such as clove, nutmeg, ginger and myrrh] and a carrier claim 1b. Further, since the claim language is open ended, then any use of two compounds amongst others would constitute prior art as discussed. The amendment will further delineate the invention which is the formulation, and narrow the claim.

SECTION 2: AMMENDMENTS TO THE SPECIFICATION

NONE

SECTION 3: AMMENDMENTS TO THE CLAIMS

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CLAIMS

What is claimed is:

- 1. A topical skin care composition comprising a safe and effective amount of:
 - a) niacin, turmeric;
 - b) garlic and / or propolis;
 - c) wormwood and / or black walnut;
 - d) aloe vera or a dermatologically acceptable carrier and;
 - e) one or more active ingredients selected from the group consisting of St. Johns wort, licorice, chamomile and herbal anti-bacterial agents. (currently amended)
- 2. A topical skin care composition according to claim 1, wherein said black walnut is further comprised of an extract derived from the species Juglans nigra or any plant from the genus Juglans, and constitutes between 0.5%-90% by weight of total composition. (currently amended)
- 3. A topical skin care composition according to claim 1, wherein said wormwood is further comprised of an extract derived from the species Artemisia Absinthium or any plant from the genus Artemisia, and constitutes between 0.5%-90% by weight of total composition. (currently amended)
- 4. A topical skin care composition according to claim 1, wherein said aloe vera or a dermatologically acceptable carrier constitutes between 5-95 % by weight of total composition. (currently amended)
- 5. A topical skin care composition according to claim 1, wherein said turmeric is further comprised of an extract derived from the species Curcuma Longa or any plant from the genus Curcuma, and constitutes between 0.5 % to 90 % by weight of total composition. (currently amended)
- 6. A topical skin care composition according to claim 1, wherein said licorice is further comprised of an extract derived from the species Glycyrrhiza Glabra or any plant from the genus Glycyrrhiza, and constitutes between 0.5 to 25 % by weight of total composition. (currently amended)
- 7. A topical skin care composition according to claim 1, wherein said St. Johns wort is further comprised of an extract derived from the species Hypericum perforatum or any plant from the genus Hypericum, and constitutes between 0.5 to 25 % by weight of total composition. (currently amended)

- 8. A topical skin care composition according to claim 1, wherein said chamomile is further comprised of an extract derived from the species Matricaria Chamomile or any plant from the genus Matricaria or Anthemis, and constitutes between 0.5 to 25 % by weight of total composition. (currently amended)
- 9. A topical skin care composition according to claim 1, wherein said garlic is further comprised of an extract derived from the species Allium sativum or any plant from the genus Allium, and constitutes between 0.75 to 70 % by weight of total composition. (currently amended)
- 10. A topical skin care composition according to claim 1, wherein said garlic further embodies a physical form of one or more selected from the group consisting of macerated, minced, diced, dried, pulverized, powdered, deodorized and shredded. (original)
- 11. A topical skin care composition according to claim 1, wherein said propolis can be substituted or combined with garlic and constitutes between 0.75 to 70 % by weight of total composition. (currently ammended).
- 12. A topical skin care composition according to claim 1, wherein said niacin is selected from the group consisting of niacinamide, nicotinic acid, nicotinamide adenine dinucleotide, nicotinamide adenine dinucleotide phosphate, nicotinamide 1,N⁶-etheneoadenine dinucleotide, 1,N⁶-etheneoadenine dinucleotide phosphate, nicotinamide guanine dinucleotide, nicotinamide guanine dinucleotide phosphate, nicotinamide hypoxanthine dinucleotide, nicotinamide hypoxanthine dinucleotide phosphate, nicotinamide mononucleotide, nicotinic acid adenine dinucleotide and nicotinic acid adenosine dinucleotide phosphate and constitutes between 0.02 to 5% by weight of total composition. (currently amended)
- 13. A topical skin care composition according to claim 1, wherein said herbal antibacterial agents are further comprised of extracts selected from the group consisting of clove, nutmeg, ginger, and myrrh, constituting between 0.5 to 25% by weight of total composition. (currently amended)
- 14. A topical skin care composition according to claim 1, wherein said dermatologically acceptable carrier is further comprised of at least one selected from the group consisting of surfactants, binders, emulsifiers, bulking agents, starches, additives, diluents, stabilizers, preservatives, emollients, foaming agents, gels, sweeteners, thickeners, vehicles, coloring agents, fragrances, solvents, moisturizers, lubricants, deodorizers and buffers. (original)
- 15. A topical skin care composition according to claim 1, wherein said dermatologically acceptable carrier is in the form of at least one selected from the group consisting of a suspension, solution, dispersion, lotion, liquid, gel, stick, capsule, foam, cream, pack, paste, coated glove or sock, salve, spray, aerosol, ointment, sponge, gel cap, granule, medicated bandage, medicated gauze, microparticles, nanospheres, microspheres, wipes, oil, powder and unique bio-delivery system. (original)
- 16. A topical skin care composition according to claim 1, wherein said dermatologically acceptable carrier is further comprised of at least one selected from a group consisting of purified

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water, lanolin, lanolin alcohols, alcohols, vitamins, methylparaben, ethylparaben, butylparaben propylparaben, glycerin, vegetable oils, polysorbate, propylene glycol, para-aminobenzoic acid, mineral oil, carbomer, phospholipids, flour, starch, sorbitan laurate, carboxylic acids, triethanolamine, talc, titanium dioxide, antioxidants, gums, petrolatum, jojoba oil, isopropyl myristate, cetyl palmitate, sorbitan stearate, acids, base, cellulose, simethicone, butylated hydroxyanisole, butylated hydroxytoluene, glycol distearate, cetearyl alcohol, sorbitol, glyceryl stearate, cetearyl octanoate, dimethicone, wax, EDTA, sodium lauryl sulfate, glyceryl dilaurate, quarterium-15, calcium sulfate, calcium chloride, metal salts, gelatin, aloe vera and imidazolidinyl urea. (original)

17-21. (previously withdrawn)

- 22. A topical skin care composition according to claim 2, wherein said black walnut constitutes about 9% by weight of total composition. (new)
- 23. A topical skin care composition according to claim 3, wherein said wormwood constitutes about 9% by weight of total composition. (new)
- 24. A topical skin care composition according to claim 4, wherein said aloe vera or a dermatologically acceptable carrier constitutes about 54% by weight of total composition. (new)
- 25. A topical skin care composition according to claim 5, wherein said turmeric constitutes about 7% by weight of total composition. (new)
- 26. A topical skin care composition according to claim 6, wherein said licorice constitutes about 3% by weight of total composition. (new)
- 27. A topical skin care composition according to claim 7, wherein said St. Johns wort constitutes about 3% by weight of total composition. (new)
- 28. A topical skin care composition according to claim 8, wherein said chamomile constitutes about 2% by weight of total composition. (new)
- 29. A topical skin care composition according to claim 9, wherein said garlic constitutes about 10% by weight of total composition. (new)
- 30. A topical skin care composition according to claim 11, wherein said propolis constitutes about 10 % by weight. (new)
- 31. A topical skin care composition according to claim 12, wherein said niacin constitutes about 1% by weight of total composition. (new)
- 32. A topical skin care composition according to claim 13, wherein said herbal antibacterial agents constitute about 2% by weight of total composition. (new)